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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,593	02/16/2001	Joseph D. Gresser	CSI-112AX	4390
23579	7590	03/22/2004		
PATREA L. PABST HOLLAND & KNIGHT LLP SUITE 2000, ONE ATLANTIC CENTER 1201 WEST PEACHTREE STREET, N.E. ATLANTA, GA 30309-3400				
			EXAMINER PREBILIC, PAUL B	
			ART UNIT 3738	PAPER NUMBER 20

DATE MAILED: 03/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

CS

Office Action Summary	Application No.		Applicant(s)	
	09/785,593		GRESSER ET AL.	
	Examiner		Art Unit	
	Paul B. Prebilit		3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONEO (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-8,11-18,20,24-31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) 5,7,8,13-15 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,6,11,12,16,25,30 and 33 is/are rejected.
- 7) ☒ Claim(s) 17,18,20,26-29 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-943) | Paper No(e)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 17, 2004 has been entered.

Specification

The disclosure is objected to because of the following informalities:

On page 1, the continuing data is not updated with the current status of the parent application and it does not give the proper relationship to the present application. The present application should be referred to as a "continuation" of the parent application.

Appropriate correction is required.

Election/Restrictions

Claims 5, 7, 8, 13-15, and 24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions or species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper Numbers 8 and 9.

It is noted that claims 13-15 and 24 are dependent upon cancelled claim 10.

Claim Objections

Claims 1 and 17 are objected to because of the following informalities:

Claim 1 is considered to be grammatically awkward in that it is unclear what elements belong to the polymer and what elements are part of the device. For this reason, the Examiner suggests making the following changes in order to make claim 1 unambiguous. On line 3 after "100%", insert --of a resorbable---. On line 3, delete "producing" and insert ---which produces--- in its place. On line 2, after "comprising", insert ---(1)---. On line 4, before "one or more", insert ---(2)---. On line 4, after "and", insert ---(3)---.

In claim 17, line 2, "material" lacks antecedence from claim 1. The Examiner suggests changing it to ---polymer---.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 6, 11, 12, 16, 25, 30, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ray (US 4,961,740) in view of Agrawal (US 5,741,329). Ray discloses a interbody spinal fusion device as claimed where the device can be made of 100% resorbable material; see the abstract, Figure 1, column 1, lines 10-22 and column 4, lines 30-45. The interior cavity of Ray is the one or more voids as claimed. However, Ray fails to specify the resorbable material used and does not teach the use of buffering

or neutralizing agents as claimed. However, Agrawal teaches that it was known to make the similar bone implants out of polylactic or polyglycolic acid polymers and to neutralize them with buffering agents such as hydroxylapatite (e.g. calcium hydroxylapatite); see the abstract, column 2, line 23 to column 3, line 59, and column 4, lines 53-64. Therefore, it would have been obvious to make the spinal implant of Ray out of the material of Agrawal for the same reasons that Agrawal uses the same in bone implants, that is, because it prevents inflammation and tissue damage; see column 1, lines 54-57. The interior cavity of Ray is the one or more voids as claimed and it can be filled with bone growth induction substances; see the abstract of Ray.

With regard to claim 25, the polymers of Agrawal can be made from mixtures of resorbable polymers; see the abstract. Therefore, it would have been obvious to use a mixture of polymer in Ray for the same reasons as Agrawal and because Applicant has not stated that it is critical to use mixtures over other polymers.

With regard to claim 30, the substantially aligned polymer molecular chains as claimed are merely a description of a crystalline polymer. For this reason, it is the Examiner's position that it would have been obvious to use a crystalline polymer as the polymer of Ray as modified by Agrawal because the crystalline polymer would have greater strength as compared to amorphous polymers.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ray and Agrawal as applied to claims 1, 3, 6, 11, 12, 16, 25, 30, and 33 above, and further in view of Brantigan (US 5,192,327). Ray discloses packing the implant with bone chips, but fails to disclose the source thereof. However, Brantigan teaches that it was known

to use patient's own bone into similar spinal implant in order to avoid using other bone graft material; see column 2, lines 44-51. Therefore, it is the Examiner's position that it would have been obvious to use the patient's own bone (i.e. autograft material) for the same reason that Brantigan teaches uses the same.

Allowable Subject Matter

Claims 17, 18, 20, 26-29 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed February 17, 2004 have been fully considered but they are not persuasive.

Applicants argue that Ray is drawn to a super-strength material yet Agrawal is not (page 8 of the response), the Examiner asserts that since Agrawal discloses bone replacements, tooth replacements, bone fracture fixation plates, screws, nails, and staples (see column 4, lines 53-64), Agrawal discloses super-strength implant materials to the extent that this language is limiting to Ray. Since Agrawal is a US Patent, it operability in the same or similar environment as the claimed device is presumed. Furthermore, it is noted that Agrawal does not require that the implant be porous; Agrawal only discloses an embodiment where the implant is porous.

In response to the assertion that the Ray and Agrawal combination would not have a reasonable expectation of success (page 9 of the response), the Examiner disagrees and notes that Agrawal is presumed to disclose operable embodiments. For

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this reason, the Examiner asserts that there is a reasonable expectation of success for the combination.

In response to applicant's arguments against the references individually (Brantigan), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In other words, Brantigan is a teaching reference, and thus, it is not required to have a resorbable device to be combinable with Ray.

Conclusion

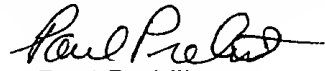
Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.


Paul Prebilic
Primary Examiner
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